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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,082	08/07/2001	Lawrence J. Marnett	N-7362 RSM	1831
32885	7590	03/08/2004	EXAMINER	
STITES & HARBISON PLLC 424 CHURCH STREET SUITE 1800 NASHVILLE, TN 37219-2376			PAK, YONG D	
			ART UNIT: 1652	PAPER NUMBER

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,082

Applicant(s)

MARNETT ET AL.

Examiner

Yong D Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Claims 1-54 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3-4 and 6-21, drawn to a method of detecting and measuring COX-2 activity, classified in class 435, subclass 25.
- II. Claim 2, drawn to a method of measuring COX-1 activity, classified in class 435, subclass 25.
- III. Claim 5, drawn to a method of distinguishing COX-2 activity from COX-1 activity, classified in class 435, subclass 25.
- IV. Claims 22-24, drawn to a method of screening for a tumor in a subject by measuring a PGH2-EA metabolite, classified in class 435, subclass 4.
- V. Claims 25-27, drawn to a method of detecting and measuring an inflammation by measuring a PGH2-EA metabolite, classified in class 435, subclass 4.
- VI. Claims 28-33, drawn to a composition comprising a label for detecting a PGH2-EA metabolite, classified in class 435, subclass 4.
- VII. Claims 34-43, drawn to a method of making an isolated PGH2-EA metabolite comprising a label, classified in class 435, subclass 4.

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- VIII. Claims 44 and 47, drawn to a an antibody against PGH2-EA metabolite and composition comprising an antibody against a PGH2-EA metabolite, classified in class 530, subclass 387.1.
- IX. Claim 45, drawn to a composition comprising a labeled PGH2-EA metabolite, classified in class 554, subclass 1.
- X. Claim 46, drawn to an antibody against a COX-2 metabolite ethanolamide, classified in class 530, subclass 387.1.
- XI. Claim 48, drawn to an antibody against a PGE2 ethanolamide, classified in class 530, subclass 387.1.
- XII. Claim 49, drawn to a method of making an antibody against PGH2-EA metabolites, classified in class 530, subclass 387.1.
- XIII. Claims 50-52, drawn to a method of measuring activity of COX-2 comprising administering AEA and measuring activity of COX-2, classified in class 435, subclass 25.
- XIV. Claim 53, drawn to a composition comprising a prostaglandin D2-ethanolamide, classified in class 554, subclass 1.
- XV. Claim 54, drawn to a composition comprising a prostaglandin D2-ethanolamide, classified in class 554, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

Inventions VI, VIII-XI and XIV-XV are patentably distinct because antibodies, labels for detecting compounds and prostaglandins are different compounds, each with its own chemical structure and function, and they have different utilities.

Inventions VIII and XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibodies of Invention VIII can be made by chemical synthesis or by recombinant technology.

The methods of Inventions I-V, VII and XII-XIII are patentably distinct as directed to materially different methods employing different products. Inventions I, III and XIII uses COX-2, Invention II uses COX-1, Inventions IV-V and VII use PGH2-EA metabolite and Invention XII uses an antibody.

Inventions I, III and XIII are patentably distinct because the methods have different effects and utilities. Invention IV-V and VII are patentably distinct because the methods have different effects and utilities.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

March 3, 2004


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER